PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

tute for form 1449/PTO

Sheet 1

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

| Complete if Known | | | | | | |
|-----------------------|---------------|--|--|--|--|--|
| Application Number | 10/606,577 | | | | | |
| Filing Date | 06/26/2003 | | | | | |
| First Named Inventor | Accola et al. | | | | | |
| Art Unit | 1634 | | | | | |
| Examiner Name | Goldberg, J. | | | | | |
| Attomey Docket Number | FORS-08167 | | | | | |

| | • | | U. S. PATENT | DOCUMENTS | |
|--------------------|--------------|--|--------------------------------|--|---|
| Examiner Initials* | Cite No.1 | Document Number Number-Kind Code ^{2 (f known)} | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| JG | 1 | ^{US-} 5,614,402 | 03/25/1997 | Dahlberg et al. | whole document |
| 1 | 2 | ^{US-} 5,795,763 | 08/18/1998 | Dahlberg et al. | whole document |
| | 3 | ^{US-} 5,843,669 | 12/01/1998 | Kaiser et al. | whole document |
| | 4 | ^{US-} 6,090,606 | 07/18/2000 | Kaiser et al. | whole document |
| | 5 | ^{US-} 6,090,543 | 07/18/2000 | Prudent et al. | whole document |
| | 6 | US- 5,846,717 | 12/08/1998 | Brow et al. | whole document |
| | 7 | ^{US-} 5,985,557 | 11/16/1999 | Prudent et al. | whole document |
| | 8 | ^{US-} 5,994,069 | 11/30/1999 | Hall et al. | whole document |
| | 9 | ^{US-} 6,001,567 | 12/14/1999 | Brow et al. | whole document |
| | 10 | ^{US-} 6,235,502 | 05/22/2001 | Weissman et al. | whole document |
| | 11 | ^{US-} 6,194,149 | 02/27/2001 | Neri et al. | whole document |
| V | 12 | ^{US-} 6,210,884 | 04/03/2001 | Lizardi | whole document |
| • | 13 | ^{US-} 6,183,960 | 02/06/2001 | Lizardi | whole document |
| | | US- | <u> </u> | | |
| | | UŞ- | | | • |
| | | US- | | | |

| | | FORE | IGN PATENT DOCU | MENTS | | |
|--------------------|--------------|---|---------------------|--|---|----|
| Examiner Initials* | Cite No.1 | Foreign Patent Document | Publication Date | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages | 70 |
| | | Country Code ³ Number ⁴ Kind Code ³ (if known) | MM-DD-YYYY | | Or Relevant Figures Appear | |
| JG | 14 | WO 98/23774 | | | | |
| 1 | 15 | WO 02/070755A2 | | | | |
| | 16 | WO 01/90337A2 | | | | |
| | 17 | WO 97/27214 | | | | |
| 1/ | 18 | WO 98/42873 | | | | |
| V | 19 | WO9850403 | | | | |

| Examiner Signature | /Jeanine Goldberg/ | Date Considered | 04415720066 |
|-----------------------|--------------------|--------------------|-------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this figure in the conformance and not considered. Include copy of this figure in the conformance and not considered. Include copy of this figure in the conformance and not considered. Include copy of this figure in the conformance and not considered. Include copy of this figure in the conformance and not considered. Include copy of this figure in the conformance and not considered. Include copy of this figure in the conformance and not considered. Include copy of this figure in the conformance and not considered. Include copy of this figure in the conformance and not considered. Include copy of this figure in the conformance and not considered. Include copy of this figure in the conformance and not considered. Include copy of this figure in the conformance and not considered. Include copy of this figure in the conformance and not considered. Include copy of this figure in the conformance and not considered. Include copy of this figure in the conformance and not considered. Include copy of this figure in the conformance and not considered. Include copy of the conformance and not considered. Include copy of the conformance and not considered. Include copy of the conformance and not considered in the through the conformance and not considered. Include copy of the conformance and not considered in the through the conformance and not considered in the conformance

Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

Sheet 2

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

| Complete if Known | | | | | |
|------------------------|---------------|--|--|--|--|
| Application Number | 10/606,577 | | | | |
| Filing Date | 06/26/2003 | | | | |
| First Named Inventor | Accola et al. | | | | |
| Art Unit | 1634 | | | | |
| Examiner Name | Goldberg, J. | | | | |
| Attorney Docket Number | FORS-08167 | | | | |

| | | | U. S. PATENT D | OCUMENTS | |
|--------------------|--|---|--------------------------------|--|---|
| Examiner Initials* | Cite No.1 | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number-Kind Code ^{2 (I known)} US- | + | | |
| | | 05- | 1_ | | |
| | | US- | | | |
| • | | US- | | | |
| | | US | | | |
| | | US- | | | |
| | - | US- | | | |
| | <u> </u> | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | - | US- | | | |
| | | US- | | | • |
| | | US- | | | |
| | | US- | | | |
| | 1 | US- | | | · |
| | | US- | | | |
| | | US- | | | |
| | | US- | | | |
| | | US- | | • | |
| | | US- | | | |

| | | FORE | IGN PATENT DOCU | MENTS | | |
|-----------------------|-------------|---|------------------|--|---|-----------|
| Examiner Initials* | Cite No. | Foreign Patent Document | Publication Date | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages | -6 |
| | | Country Code ³ "Number ⁴ "Kind Code ⁵ (if known) | MM-DD-YYYY | | Or Relevant Figures Appear | Ľ |
| JG | 20 | WO0198537 | | | | <u> </u> |
| | | | | | | ┡ |
| | | | | | | _ |
| | | | | | | - |
| | | | | | | L |
| | | | • | | | |

| Examiner Signature | /Jeanine Goldberg/ | Date Considered | 04/15/2006 |
|-----------------------|--------------------|--------------------|------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this examination of the part of the paper of the pape

Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

PTO/SB/08B (08-03)

Approved for use through 07/31/2008. OMB 0851-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
p. a collection of Information unless it contains a valid OMB control number.

| Substitu | ite for form 1449/PTO | | | Complete if Known | | |
|-----------------------------------|------------------------|-------|-----------|------------------------|----------------|--|
| Judania | 10/10/11/1443// 70 | | | Application Number | 10/606,577 | |
| INF | ORMATION | N DIS | CLOSURE | Filing Date | 06/26/2003 | |
| STA | STATEMENT BY APPLICANT | | | First Named Inventor | .Accola et al. | |
| | | | | Art Unit | 1634 | |
| (Use as many sheets as necessary) | | | ecossary) | Examiner Name | Goldberg, J. | |
| Sheet | 3 | of | 5 | Attorney Docket Number | FORS-08167 | |

| | | . NON PATENT LITERATURE DOCUMENTS | |
|-------------------------|--------------|---|----|
| Examiner Initials* | Cite No.1 | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published: | T² |
| JG | 21 | Heim, et al., Genetics in Medicine 3(3):168-176 (2001) | |
| | 22 | Raman, et al., Pediatrics 109(1): E13 (2002) | |
| | 23 | Dumur, et al., Hum Genet 97: 7-10 (1996 | |
| | 24 | Grody, Cutting, et al., Genetics in Medicine 3(2):149-154 (2001) | |
| | 25 | Grody and Desnick, Genetics in Medicine 3(2):87-90 (2001) | |
| | 26 | Rosenstein and Cutting, Journal of Pediatrics 132(4): 589-595 (1998) | |
| | 27 | LeGrys, Laboratory Medicine 33(1): 55-57 (2002) | |
| | 28 | Wilson, et al., Journal of Pediatrics 132 (4): 596-599 (1998) | |
| | 29 | Gregg, et al., Pediatrics 99(6): 819-824 (1997) | |
| $\overline{\mathbf{V}}$ | 30 | Rock, et al., Pediatrics 85(6): 1001-1007 (1990) | |

| | | | |
|--------------------|--------------------|--------------------|------------|
| Examiner Signature | /Jeanine Goldberg/ | Date Considered | 04/15/2006 |

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English tanguage Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08B (08-03)

Approved for use through 07/31/2006. OMB 0851-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
as collection of information unless it contains a valid OMB control number.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| | ute for form 1449/PTO | - | | Complete If Known | | |
|-----------------------------------|-----------------------|-----------|------------|------------------------|----------------|--|
| Coodin | | | | Application Number | 10/606,577 | |
| INF | ORMATION | N DIS | CLOSURE | Filing Date | 06/26/2003 | |
| STATEMENT BY APPLICANT | | | PPLICANT | First Named Inventor | .Accola et al. | |
| (Use as many sheets as necessary) | | | | Art Unit | 1634 | |
| | (Ose as many sn | 0013 83 7 | (octasary) | Examiner Name | Goldberg, J. | |
| Sheet | 4 | of | 5 | Attorney Docket Number | FORS-08167 | |

| Examiner Initials* | Cite No.1 | NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | |
|-------------------------|--------------|--|--|--|
| JG | 31 | Kerem, et al., Science 245: 1073-1080 (1989) | | |
| | 32 | Riordan, et al., Science 245: 1066-1073 (1989) | | |
| | 33 | Rommens, et al., Science 245: 1059-1065 (1989) | | |
| | 34 | Bobadilla, et al., Human Mutation 19: 575-606 (2002) | | |
| | 35 | Noone and Knowles, Respiratory Research 2(6):328-332 (2001) | | |
| | 36 | Rohlfs, et al., Genetics in Medicine 4(5):319-323 (2002)) | | |
| | -37 | Kiesewetter, et al., Nature Genetics 5(3): 274-278 (1993) | | |
| | 38 | Fujimura, Northrup et al. N Engl J Med., Jan 4, 322(1):61 (1990) | | |
| | 39 | Lyamichev et al., Nat. Biotech., 17:292 (1999) | | |
| $\overline{\mathbf{V}}$ | 40 | Hall et al., PNAS, USA, 97:8272 (2000) | | |

| Examiner Signature | /Jeanine Goldberg/ | Date Considered | 04/15/2006 |
|-----------------------|--------------------|--------------------|------------|

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08B (08-03)

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
b a collection of information unless it contains a valid OMB control number. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a c

| Substitute for form 1449/PTO | | | | Complete if Known | | |
|-----------------------------------|----------------------|-----|---------|------------------------|---------------|---|
| JUDSHILL | 10 10 10 11 1440/ 10 | | | Application Number | 10/606,577 | |
| INF | ORMATION | DIS | CLOSURE | Filing Date | 06/26/2006 | |
| STATEMENT BY APPLICANT | | | | First Named Inventor | Accola et al. | |
| | <i>a</i> | | | Art Unit | 1634 | |
| (Use as many sheets as necessary) | | | | Examiner Name | Goldberg, J. | |
| Sheet | 5 | of | 5 | Attorney Docket Number | FORS-08167 | J |

| Examiner Initials* | Cite No.1 | NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue | T ² | | | |
|-----------------------|--|---|----------------|--|--|--|
| | number(s), publisher, city and/or country where published. | | | | | |
| JG | 41 | Reynaldo et al., J. Mol. Biol. 97: 511-520 (2000) | | | | |
| | | | | | | |
| | ž.,,,, | | | | | |
| | | | _ | | | |
| | | | | | | |
| | | | | | | |
| | | | <u> </u> | | | |
| | | · | L | | | |
| | | | | | | |
| | | | | | | |
| | <u> </u> | | | | | |
| | | | | | | |
| | | | | | | |

| Examiner Signature | /Jeanine Goldberg/ | Date Considered | 04/15/2006 |
|-----------------------|--------------------|--------------------|------------|
| | | | |

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant,

considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1,98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1,14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.